



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/333,256      | 06/15/1999  | JURGEN ENGEL         | PM26021897/2        | 3896             |

7590 04/15/2002

PILLSBURY MADISON & SUTRO LLP  
INTELLECTUAL PROPERTY GROUP  
1100 NEW YORK AVENUE NW  
NINTH FLOOR EAST TOWER  
WASHINGTON, DC 200053918

EXAMINER

TRAN, SUSAN T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 04/15/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/333,256

Applicant(s)  
Engel et al.

Examiner  
Susan Tran

Art Unit  
1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Mar 18, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

Art Unit: 1615

### ATTACHMENT

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99, Requested for Extension of Time filed 08/28/00, 05/07/01, and 03/18/02, Amendment A filed 08/28/00, Amendment B filed 10/24/00, Notice of Appeal filed 05/07/01, and Request for Reconsideration filed 03/18/02.

### *Claim Rejections - 35 U.S.C. § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. US 5,905,149.

Battistini discloses a film-coated tablet composition comprising diluents, e.g., lactose, corn starch, or cellulose; lubricants, e.g., magnesium stearate, silica; and binding agents, e.g., starches, or cellulose (column 11, lines 1-30). The composition further comprising antitumor agent, e.g., cyclophosphamide (column 12, lines 4-8).

Art Unit: 1615

*Claim Rejections - 35 U.S.C. § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al., in view of Eugster et al. US 5,593,691.

Battistini is relied upon for the reasons stated above. Regarding to claims 4-6, the cited reference is silent as to the teaching of the amounts of the ingredients.

Eugster teaches a coated tablet composition comprising active agent; excipient, filler; binder such as corn starch; flow-control; talc or magnesium stearate (column 21, lines 32 through column 22, lines 1-11). The active agent is an antitumor agent, e.g., cyclophosphamide (column 11, lines 54-56). The amounts of the ingredients are disclosed in column 32, lines 30-35. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Battistini's tablet composition using the amounts for the ingredients in view of the teaching of Eugster. The reason for this modification is to obtain a stable film coated tablet of cyclophosphamide.

The exclusion of preswollen starch does not impart patentable distinct, since the prior art obtains the same results desired by applicants, i.e., a coated tablet containing phosphamide having excellent stability and bioavailability. Thus, it would have been obvious for one of the

Art Unit: 1615

ordinary skill in this art to, by routine experimentation determine a suitable type of starch to obtain a stable composition of phosphamide, since phosphamide is known to the skill in the art to be an unstable active compound.

*Response to Arguments*

3. Applicant's arguments filed 03/18/02 have been fully considered but they are not persuasive. The examiner maintains the original rejections.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. US 5,905,149.

Applicant argues that Battistini does not provide examples showing the exclusion of pre-swollen starch as a dry binder. Contrary to the applicant's argument, Battistini's example 7 shows a very small amount of pre-swollen corn starch (10 grams out of 415 grams used), does not impart patentable distinct over the claimed limitation of "no preswollen starch is present as a dry binder". Battistini discloses starch as diluent, as disaggregating agent, and also as binding agent, therefore, 10 grams of pre-swollen starch could have been used as diluent and/or disaggregating agents; and the remainder of 405 grams of corn starch could have been used as dry binder. Furthermore, the issued of Battistini was based on the teaching within the four walls patent, Battistini cannot be limited on his best mode as described in the examples

Applicant argues that because Battistini does not teach the claimed amounts of the ingredients, the invention is not anticipated by Battistini. The 102(e) rejection over claims 4-6

Art Unit: 1615

has been withdrawn. However, the examiner maintains the original 102(e) rejection over claims 1-3 because the claimed amounts of the ingredients are not recited in the rejected claims.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al., in view of Eugster et al. US 5,593,691.

Applicant argues that neither one of the references address the stability problem. Contrary to the applicant's argument, Eugster does recognize the advantageous result of obtaining a stable composition, therefore, excipients, diluents, and/or stabilizers have been used (see column 20, lines 40-60; and column 22, lines 7-9). Accordingly, Eugster does suggest the stability characteristics of the pharmaceutical composition comprising antitumor agent, e.g., cyclophosphamide. Hence, it would have been obvious for one of ordinary skill in the art to modify Battistini in view of the teaching of Eugster to obtain a stable composition containing cyclophosphamide and excipient, binder, and/or stabilizer. Furthermore, applicant's specification in page 2, lines 9-13, discloses "[it] was moreover surprising that the finished film coated tablets exhibit an adequate stability". Battistini teaches film coated tablet (column 11, lines 1-2).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1615

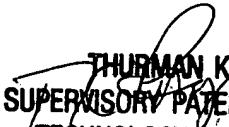
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600